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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,651	03/29/2004	Peter Gilbert	J-3776A	2445

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EXAMINER	
PETERSEN, CLARK D	

ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,651	GILBERT ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (J Clin Pathol, 1993). Jones describes producing bacterial aggregates from coagulase negative staphylococci and various plant lectins. Specifically staphylococci were isolated from hospital patients and grown on tryptone agar. The expanded bacterial cultures were then suspended in 3 ml PBS. Suspended bacteria were added to wells of a microtiter plate in 50 μl drops. An equal amount of solubilized lectin was added (see Method, p. 761, for example). Bacterial agglutination occurred in response to at least one of four applied lectins in 93% of the bacterial strains that were tested (see Results, p. 762, for example); this could be observed in the form of a bacterial aggregate that sometimes covered the bottom of the microtiter well (see Methods, p. 762, col. 2, for example). One of the lectins that induced bacterial aggregation was Concanavalin A (see Results, p. 762, for example). In this particular experiment individual strains of coagulase negative staphylococci were isolated from different patients; therefore the bacterial aggregates were homogeneous. Therefore the teachings of Jones are deemed to anticipate the instant claims 1-4 and 10-12.

Claims 1-4 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Liljemark et al (Infection and Immunity, 1981). Liljemark et al teach a method of testing aggregation and adherence of oral streptococci to hydroxyapatite beads. Specifically, they compare the effect of bacterial aggregation in response to added lectins or saliva; they demonstrate that it is possible to induce bacterial aggregation in individual species in response to concavalin A, for example (see p. 936, col. 1, for example). Therefore the teachings of Liljemark et al are deemed to anticipate the instant claims 1-4 and 10-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljemark et al (Infection and Immunity, 1981). The teachings of Liljemark et al are discussed above and applied as before.

Liljemark et al do not expressly teach the combination of two different types of oral streptococci in an aggregation by inducing agglutination with Concavalin A. However they teach that the *Streptococcus mitis* and *Actinomyces viscosus* can be coaggregated and induced to bind to hydroxyapatite beads coated with saliva (see Fig.

7, p. 939, for example). They also state that the aggregating effects of the Streptococcus species in response to concavalin A was very similar to that induced by saliva (see p. 938, col. 1, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lectins in a method taught by Liljemark of coaggregating bacteria on hydroxapatite beads, because Liljemark teaches that lectins and saliva have very similar profiles in inducing bacterial aggregation, and Liljemark also teaches that heterogeneous aggregates are readily induced by saliva. One would have been motivated to do so for the expected benefit of producing heterogeneous bacterial aggregates relevant to the study of oral bacteria biofilms.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Claims 1-4, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Hussain et al (J Med Microbiol, 1992). The teachings of Jones et al are discussed above and applied as before.

Jones et al do not expressly teach the measuring of bacterial viability within an aggregate in the presence of a biocide.

Hussain et al teach a method of growing a bacterial slime comprising coagulase negative streptococci isolates. They then expose the slime to a battery of antibiotics and measure the inhibitory effect on bacterial metabolism through measurement of

uptake of radiolabeled glucose in isolated slime fragments (see Materials and methods, p. 64, for example). Hussain et al note that some antibiotics had no effect on biofilm formation, but bacterial metabolism could still be measured through radiolabeled glucose uptake (see Results, p. 67; see Fig. 2, as examples). Therefore, their experiments read on exposing a bacterial aggregate to a biocide and measuring viability of the bacteria within the aggregate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure antibiotic action of a substance against cells within a bacterial aggregate as taught by Hussain et al, using an aggregate formed by addition of lectins to a bacterial suspension taught by Jones, because Jones et al teaches that it is possible to form bacterial aggregates through addition of lectins such as concanavalin A, and Hussain et al teach that it is possible to expose bacterial aggregates to antibiotics and measure their metabolic function. One would have been motivated to do so because it is well known in the art that response of bacteria in aggregates to antibiotics is different than the response of individual, suspended bacteria.

Claims 1-3, 5-7, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Lamont et al (Infection and Immunity, 1990) and Wu et al (J Bacteriol, 1995). The teachings of Jones are discussed above and applied as before.

Jones does not expressly teach the sequential aggregation of bacteria to form a lamellar aggregate.

Lamont et al teach a method of preparing a lamellar aggregate of oral bacteria. Lamont et al describe a method of coating a piece of nitrocellulose with one bacterial species. They then apply a second, radiolabeled species on top of the initial layer to form a lamellar, hetereogeneous aggregate (see Materials and Methods, pp. 1738-1739, for example). They can measure the successful formation of a bilayer, multispecies aggregate on nitrocellulose. Lamont et al note that addition of lactose, which is an inhibitor of lectin-like interactions, appeared to have no effect on their observation of multispecies, lamellar aggregate formation (see Discussion, p. 1742, for example). They expressly state that multiple mechanisms are likely involved in lamellar aggregate formation (see p. 1742, col. 1, for example). It is noted that the species that one species that is used in the study is *S. sobrinus*.

Wu et al teach that *S. sobrinus* produces endogenous lectins that help it aggregate with other bacteria, and additionally secrete lectins into their growth medium (see Introduction, p. 1399, for example). They demonstrate that by controlling the amount of lectins produced and/or secreted by the bacteria, they can control aggregate formation (see Table I, p. 1400; see Fig. 1and 2, p. 1400; see Fig. 3, p. 1401, as examples). They demonstrate that with the particular species employed by Lamont et al, lectins play an essential role in bacterial aggregation in the correct experimental conditions.

It would have been obvious to one of ordinary skill in the art to prepare a multilayer bacterial aggregate in a method taught by Lamont et al using lectins as taught by Jones, because Lamont et al teach that is possible to make a lamellar aggregate by

interspecies agglutination, and Jones teaches that agglutination can be achieved by addition of exogenous lectin; furthermore, Wu et al teach that lectins in fact play an important role in at least some bacterial aggregation, particularly with at least one species that Lamont et al demonstrate can participate in forming a lamellar layer. One would have been motivated to do so for the expected benefit of studying formation of a multispecies lamellar layer, which is known in the art to occur in medically relevant situations, such as colonization of the oral cavity which can lead to tooth decay.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Jones in view of Lamont et al (Infection and Immunity, 1990) and Wu et al (J Bacteriol, 1995) and Hussain et al (J Med Microbiol, 1992). The teachings of the cited references are discussed above and applied as before.

Jones, Lamont et al and Wu et al do not expressly teach the application of biocides to a lamellar aggregate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test biocides as taught by Hussain et al on a lamellar aggregate made with lectins, as taught by Lamont et al, because Lamont et al teach that is possible to make a lamellar aggregate, Wu et al teach that aggregation of the species employed by Lamont et al can be facilitated with lectins, and Jones teaches the formation of aggregates with exogenous, and Hussain et al teach that it is desirable to

test antibiotics on biofilms. One would have been motivated to do so for the expected benefit of testing biocides on a clinically relevant model, because it is known in the art that many types of bacteria, such as oral streptococci, form interspecies lamellar aggregates.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP

9/30/2006

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER